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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,046	10/21/2005	Brent Vernon	16546.1.2	8309

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

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01/07/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,046	VERNON ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *1-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of response to election/restriction requirement filed 8/31/09, IDS filed 2/13/06. Claims 1-55 are pending.

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 28-55 in the reply filed on 8/31/09 is acknowledged.

2. Applicant has further elected polypropylene glycol diacrylate as the component containing unsaturated bond and pentaerythritol-tetrakis-3-mercaptopropionate as the nucleophilic component. Applicant has also identified claim 29-47 and 50-55 as reading on the elected species. Therefore, claim 28-47 and 50-55 are examined. However, because PEGDA is one of the acrylates in the art, claims 48 is examined and claims 47 and 59 are rejected as being obvious substitution for PEDGA. Thus, claims 28-55 are under examination.

3. And claims 1-27 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/31/09.

4.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 47-49, 51 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 47-49 recite the limitation "the acrylate precursor" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim. Claim 29 upon which claims 47-49 depend from does not recite "acrylate precursor."

8. Claim 51 recites the limitation "the base" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 51 depends on claim 42 and claim 42 depends from claim 28. Neither claim 42 nor claim 28 recites the presence of a base in the composition.

9. Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. The boundaries of protection sought for other abnormal vasculature in claim 55 is not clear making claim 55 indefinite.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 28-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whalen, II et al. (US 6,645,167) or Greff et al. (US 5,667,767) and Haldimann (US 6,428,576 B1) and Verduyn Lunel ("Significance of annulus fibrosus of heart in relation to AV conduction and ventricular activation in cases of Wolff-Parkinson-White syndrome," in British Heart Journal, 1972, 34, 1263-1271) in view of Vernon et al. ("Water-borne, in situ cross-linked biomaterials from phase-segregated precursors," in J. Biomed. Material Res., Mar 1 2003, 64(3), pp 447-456).

14. Whalen describes method of embolizing blood vessels using embolic compositions comprising biocompatible polymer, biocompatible water insoluble contrast agent and biocompatible solvent (see the whole document with emphasis on the abstract, columns 7 and 8 for the polymers). These polymer comprise nucelophilic components and components having conjugated unsaturated bonds.

15. Greff discloses composition for embolizing blood vessels, the composition comprises polymer that polymerize in situ (see the whole document with emphasis on the abstract, column 4 for the monomeric components that polymerize in situ; column 5, lines 8-15 for the solvent; column 6).

16. Haldimann discloses method for ameliorating effects of annulus fibrosus using in situ curable compositions, the composition comprises the polymers listed in columns 5 and 6 (see the whole document with emphasis on columns 5 and 6; column 12, lines 52-65; Examples 3 and 4 uses pentaerythritol tetrakis (3-mercaptopropionate)(QT) and polyethylene glycol diacrylate (PEGDA), which are the nucleophilic component and the component having conjugated

unsaturated bond of the claims. QT meets claims 28-31, 35-38. PEGDA meets claims 28, 32-35, 37, 38 and 48. Claims 42 and 43 recite the properties of the composition. Examples 3 and 4 of Haldimann has phosphate buffer and thus meets claim 39 and 50; Example 4 also has NaOH base meeting claims 41 and 51. Embolic compositions are known to contain contrast agents for detection such as is disclosed by Greff and Whalen so that claims 44 and 50 are met. With regards to claims 49 and 47, one acrylate can be used in place of the other with the expectation that the unsaturated bond would undergo Michael type addition with the nucleophilic agent or QT. Whalen describes using balloon catheter for introduction of the embolic composition (abstract; column 3, lines 20-55, 58) meeting 53, 54. For claim 55, Verduyn Lunel teaches that annulus fibrosus is related to AV of the heart (see at least the title) and this is related to Haldimann's method of introducing the composition comprising buffer, QT and PEGDA.

17. While the claimed composition is known in the art, and while Greff and Whalen teach methods and compositions for embolizing blood vessels, neither Greff nor Whalen teach the use of the claimed composition for embolizing blood vessels. Haldimann use the composition to treat annulus fibrosus as described above and this is related to AV of the heart. Furthermore, Vernon teaches the use of QT and PEGDA to form in situ polymer.

18. Therefore, taking the teachings of Whalen, Greff, Haldimann and Vernon, one having ordinary skill in the art at the time the invention was made would reasonably expect that the composition of Vernon or Haldimann introduced to vascular site would gel in situ as embolic compositions for anticipated embolization of vascular sites and annulus fibrosus.

19. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618